K032138
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10 510(K) SUMMARY

Applicant:	Medtronic Gastroenterology and Urology 4000 Lexington Ave N Shoreview, MN 55126
Contact:	Julie Goode Senior Regulatory Affairs Specialist Medtronic Gastroenterology and Urology 4000 Lexington Ave N Shoreview, MN 55126 (763) 514-9670 (763) 514-9703
Trade Name:	Medtronic Single Use Esophageal Manometric Catheter and Medtronic Single Use Anorectal Manometric Catheter
Common Name:	Esophageal Manometry Catheter
Classification Name:	Monitor, Esophageal Motility, and Tube 21 CFR 876.1725
Name of Predicate Device	Zinetics EMC Esophageal Manometric Catheter (K884527) Zinetics Anorectal Manometric Catheter (K921682) Mediplus Esophageal Manometry Catheter (K013704) Latitude Esophageal Pressure Catheter and Latitude Ano-Rectal Pressure Catheter (K022023)

Device Description

The Medtronic Single Use Esophageal Manometric Catheter is intended for water-perfused manometry of the GI tract. The Medtronic Single Use Anorectal Manometric Catheter are intended for water-perfused manometry of the rectal and anal tract.

These catheters consist of a multi-lumen PVC tube connected to multiple PVC capillary tubes. The capillary tubes connect to pressure transducers of an infusion system that perfuses each lumen of the catheter with water. Pressure measurements are made at side holes in the multi-lumen PVC tube along the gastro-intestinal tract. A silicone balloon is attached to the end of the catheter body of the anorectal model.

Performance Standards

No applicable mandatory performance standards or special controls exist for this device.

Statement of Intended Use

The Medtronic Single Use Esophageal Manometric Catheter is intended for water-perfused manometry of the GI tract.

The Medtronic Single Use Anorectal Manometric Catheter is intended for water-perfused manometry of the rectal and anal canal.

Substantial Equivalence

This premarket notification is being submitted for the Medtronic Single Use Esophageal Manometric Catheter and Medtronic Single Use Anorectal Manometric Catheter. Other manometry catheters, previously cleared by FDA, and currently marketed include:

- Zinetics EMC Esophageal Manometric Catheter (K884527, February 28, 1989)
- Zinetics Anorectal Manometry Catheter (K921682, December 29, 1994)
- Mediplus Esophageal Manometry Catheter (K013704, August 5, 2002)
- Latitude Esophageal Pressure Catheter and Latitude Ano-Rectal Pressure Catheter (K022023, January 7, 2003)

Summary of Testing

The materials used in the Medtronic Single Use Esophageal Manometric Catheter and in the Medtronic Single Use Anorectal Manometric Catheter have been tested for biocompatibility and meets the requirements of ISO 10993-1.

In-vitro testing was performed to support substantial equivalence to the predicate devices. The results of this testing indicate that the Medtronic Single Use Esophageal Manometric Catheter and Medtronic Single Use Anorectal Manometric Catheter meet all of the design and performance requirements.

Conclusion

Through the data and information presented, as well as similarities to a legally marketed device, Medtronic, Inc. considers the Medtronic Single Use Esophageal Manometric Catheter and the Medtronic Single Use Anorectal Manometric Catheter to be substantially equivalent to the previously discussed legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Ms. Deborah Kidder
Regulatory Affairs Specialist
Medtronic Gastroenterology and Urology
4000 Lexington Avenue North
SHOREVIEW MN 55126-2983

Re: K032138
Trade/Device Name: Medtronic Single Use Esophageal and Anorectal Manometric Catheters; Models 9012P1201, -11, -21, -31, -41, -51, -61, and -71; 9012P1301, -11, -21, -31, and -41
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: 78 KLA
Dated: July 10, 2003
Received: July 11, 2003

Dear Ms. Kidder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K032138

Device Name: **Medtronic Single Use Esophageal Manometric Catheter**
Medtronic Single Use Anorectal Manometric Catheter

Indications for use:

The Medtronic Single Use Esophageal Manometric Catheter is intended for water-perfused manometry of the GI tract

The Medtronic Single Use Anorectal Manometric Catheter is intended for water-perfused manometry of the rectal and anal canal.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032138